



The Procter & Gamble Company
Health Care Research Center
8700 Mason Montgomery Road
Mason, Ohio 45040-9462
www.pg.com

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April 04, 2005

Division of Dockets Management
Food and Drug Administration
Center for Drug Evaluation and Research
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Sir or Madam:

Attached are three copies for inclusion in Docket 1982N-0166 of comments that Procter & Gamble is submitted regarding the Agency's proposal to amend the tentative final monograph for drug products containing bismuth subsalicylate regulated under the "Overindulgence" Monograph to include two new symptom relief indications. If you have any questions feel free to contact me at the letterhead address above or telephone number below.

Sincerely,
The Procter & Gamble Company
Product Safety and Regulatory Affairs Department

Kevin T. McLaughlin
Senior Regulatory Affairs Manager
Personal Health Care
(513) 622-2420

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Procter & Gamble

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8700 Mason-Montgomery Road, Mason, Ohio 45040-9462

April 04, 2005

Dockets Management Branch
U. S. Food and Drug Administration, HHS
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 1982N-0166
Orally Administered Drug Products for Relief of Symptoms Associated With
Overindulgence in Food and Drink for Over-the-Counter Human Use; Proposed
Amendment of the Tentative Final Monograph

Dear Sir or Madam:

The Procter & Gamble Company (Procter & Gamble) herewith submits, in triplicate, comments in response to the proposed rule: Orally administered drug products for relief of symptoms associated with overindulgence in food and drink for over-the-counter (OTC) human use ("Overindulgence Monograph"); proposed amendment to the tentative final monograph (TFM), published on January 5, 2005 in the Federal Register (Vol. 70, No. 3, pages 741-746). Procter & Gamble, as a manufacturer and distributor of Pepto-Bismol® a drug product for OTC human use that is regulated pursuant to this monograph, is directly affected by this proposed amendment to the tentative final monograph.

Procter & Gamble supports the Food and Drug Administration (FDA) proposal to amend the tentative final monograph for OTC drug products associated with overindulgence in food and drink to include "for the relief of upset stomach associated with" "belching" and "gas" "due to overindulgence in food and drink" as indications for bismuth subsalicylate containing drug products. This amendment will provide an effective therapy for the treatment of these two additional symptoms associated with overindulgence in food and drink.

Being the FDA has proposed to add these two symptoms for products containing bismuth subsalicylate, this obviates Procter & Gamble's earlier comment of July 8, 2004, which proposed to permit a drug product containing bismuth subsalicylate in combination with simethicone, with simethicone present as the "anti-gas" active ingredient. Thus, Procter & Gamble does not propose to conduct clinical investigations of a bismuth subsalicylate/simethicone combination at this time.

Procter & Gamble encourages the FDA to expeditiously amend the Overindulgence Monograph for these two symptoms as well as to complete its review of Procter & Gamble's other comments and data in our submission dated July 8, 2004 as part of the Agency's on-going rule-making for drug products regulated under this monograph.

Sincerely,
The Procter & Gamble Company
Product Safety and Regulatory Affairs Department

Kevin T. McLaughlin
Senior Regulatory Affairs Manager
Personal Health Care
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